Bringing **Science** to the *Art* of Dentistry™

K103514

MAY 25 2011

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6000 Fax: 847-534-6111
Date Prepared:	24 November 2010
Trade Name:	**Pro-V Coat**
Common Name:	Separating Agent
Product Code:	EBG
Classification/Name:	Temporary Crown and Bridge Resin **Class II per 21 CFR 872.3770**

Predicate Device:

Pro-V Coat is substantially equivalent to Pro-V by Bisco, Inc. Schaumburg IL K073263

Indications for Use:

Pro-V Coat is indicated for use as a separating agent when placed between any resin based material and to the substrate to which permanent bonding is not desired, such as:

1. any resin based material to the adhesive layer.
2. any resin based material to the remaining tooth structure.

Description of Applicant Device:

Pro-V Coat is a water soluble separating agent that effectively prohibits bonding of the resin-based material used for temporary restorations to the adhesive interface or to the remaining tooth structure. Pro-V Coat along with the temporary restoration will remain in place for a certain period of time. The temporary restorative material is easily removed with hand instruments and the Pro-V Coat is rinsed off with copious amounts of water. Pro-V Coat is designed to clean up effortlessly without any residue. Pro-V Coat will not compromise subsequent adhesion of the final restoration.

Technological Characteristics

All components of Pro-V Coat are found in the legally marketed predicate device Pro-V K073263, (referenced in this submission as the predicate). A comparison of the chemical composition of Pro-V Coat to the predicate is provided in Table 1:

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510 (k) SUMMARY (Continued)

Table 1:

Chemical Composition	Predicate	Pro-V Coat
Water soluble	X	X
Contains volatile solvent	X	X

Performance Data:

The physical/mechanical properties of Pro-V Coat were tested in the lab using R&D testing protocols. The information provided in this 510(k) of Pro-V Coat compared to the predicate demonstrated that Pro-V Coat was an effective separating agent and that it inhibited bonding between the adhesive / tooth structure and the restorative material. A comparison of the physical/mechanical properties is included in Table 2.

Table 2:

Physical / Mechanical Property Comparison	Predicate	Pro-V Coat
Low viscosity	X	X
Water soluble	X	X

Biocompatibility:

An evaluation of biocompatibility was conducted to determine the safety of the Pro-V Coat using FDA and internationally recognized guidelines ISO 10993-1. The conclusion of the safety evaluation and subsequent cytotoxicity testing is that Pro-V Coat is safe for its intended use.

Conclusion:

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to the other legally marketed device Pro-V K073263. It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

MAY 25 2011

Re: K103514
Trade/Device Name: Pro-V Coat
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: May 18, 2011
Received: May 20, 2011

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K10 3514

Device Name: Pro-V Coat

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1. any resin based material to the adhesive layer.
2. any resin based material to the remaining tooth structure.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103514